EXHIBIT

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: ***Genevieve Schwartz v. Ethicon, Inc., et al.*** ***2:12-cv-06184***	**HON. JOSEPH R. GOODWIN**

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and

pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT mid-urethral sling.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT played in causing injury to Ms. Schwartz. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Schwartz. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Schwartz.

B. Summary of Materials Reviewed

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Genevieve Schwartz:

Advanced Plastic Surgery Center

Arizona Pain Institute

Bellezza Women's Health

Chino Valley Medical Center

Phoenix Gynecology Consultants, LLC

Prescott Urology

Prescott Women's Clinic

Sonora Quest Laboratories – Tempe

St. Joseph's Hospital and Medical Center

Yavapai Regional Medical Center

Deposition of Genevieve Schwartz

Plaintiff Profile Form and Plaintiff Fact Sheet of Genevieve Schwartz

C. Summary of Medical Facts related to Genevieve Schwartz

DOB: 10/6/1938

Past Medical History:

CAD, DJD, Anxiety, Depression, MI, Hemorrhoids

Past Surgical History:

Hysterectomy, Episiotomy, Anxiety, Hyperlipidemia, Oophorectomy, Heart Catherization, LSO for Ectopic, Urethropexy (1985), Appendectomy,

Social:

No Tobacco

Medications:

Prempro, Paroxetine, Valium, Zocor, Caduet

Deposition

She had recurrent UTIs. She was taking Macrobid in 2001 for chronic UTIs.

She has been using different HRT replacement as her son is a gynecologist.

2/14/2007

She underwent placement of TVT-O for stress urinary incontinence.

12/17/2010

She had a hysteroscopy for postmenopausal bleeding.

1/19/2011

She reports urinary pressure and UTI.

4/4/2011

She was treated for an UTI.

7/25/2011

Valley Urogynecology. Since the age of 17, she reports UTIs. She reports surgery for her bladder in 1985 that lasted 15 years and this gradually has returned. She reports in February 2007 a sling and she feels that it has been unsuccessful. She reports heaviness in the abdominal and pelvic area.

7/29/2011

She was seen for mesh erosion.

10/7/2011

She was seen by Dr. Marshburn and had a mesh erosion.

12/12/2011

She was seen for incontinence, UTIs and mesh exposure. On examination there was a tanged caudal edge on the distal aspect of transobturator sling protruding through the vagina that occurred from sulcus to sulcus. Her sling was cut and excised.

1/25/2012

She had her bladder mesh removed and is leaking urine. She had emergency back surgery.

2/3/2012

She has mixed UI with cystocele.

8/6/2012

She has been treated by her urogynecologist for 6 months on Bactrim. She never used Enablex.

8/13/2012

Reports dysuria and she is unsure if Toviaz is working. Urine culture.

6/30/2015

Nephrology Referral: fluid retention.

3/8/2017

She reports that Dr. Marshburn suggested that her urethra had significant scarring. She reports mixed UI. She had a normal examination. She was restarted on Toviaz.

D. Methodology and Analysis.

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and dyspareunia suffered by Genevieve Schwartz, her TVT sling contributed to her pain, vaginal scarring, and erosion. She reports pain over the sling on examination. On physical examination it appears the edge of the sling is eroding through the vagina.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her tubal ligation and hysterectomy. I also considered other factors in her history including her previous Hysterectomy, Episiotomy, Anxiety, Hyperlipidemia, Oophorectomy, Heart Catherization, LSO for Ectopic, Urethropexy (1985) and Appendectomy. I also considered her Hemorrhoids and depression. I considered each of these other risks for her pain, dyspareunia, and mesh erosion, and I concluded that they could be ruled out as a source of her pain, dyspareunia, and mesh erosion suffered by Genevieve Schwartz.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Genevieve Schwartz's treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

E. Conclusion.

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Schwartz' s pain, dyspareunia, and mesh erosion is related to her TVT Mesh Implant. This pain is related to what Dr Elliott described as a chronic inflammation around the mesh with resulting scarring as described by Dr. Marshburn. As per Dr. Klinge's opinion there may be safer alternatives to Gynecare's polypropylene (i.e. laser cut technology less fraying or different materials (PVDF). Ethicon's mesh is designed to cause a greater than necessary inflammation and foreign body reaction as is occurring in Ms. Schwartz.

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I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22th day of May, 2017.

William Porter, M.D.